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TITLE: Low profile catheter with expandable outer tubular member

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Brief Summary Text - BSTX (2):
This invention generally relates to intravascular **catheters, such as balloon** dilatation catheters used in percutaneous transluminal coronary angioplasty (PTCA).

Brief Summary Text - BSTX (5):
Another type of over-the-wire dilatation catheter is the **rapid exchange** type catheter, which was introduced by ACS under the trademark ACS RX.RTM. Coronary Dilatation Catheter. It is described and claimed in U.S. Pat. No. 5,040,548 (Yock), U.S. Pat. No. 5,061,273 (Yock), U.S. Pat. No. 4,748,982 (Horzewski et al.) and U.S. Pat. No. 5,154,725 (Leopold) which are incorporated herein by reference. This dilatation catheter has a short **guidewire** receiving sleeve or inner lumen extending through a distal portion of the catheter. The sleeve or inner lumen extends proximally from a first **guidewire** port in the distal end of the catheter to a second **guidewire** port in the catheter spaced proximally from the inflatable member of the catheter. A slit may be provided in the wall of the catheter body which extends distally from the second **guidewire** port, preferably to a location proximal to the proximal end of the inflatable

balloon. The structure of the catheter allows for the **rapid exchange** of the catheter without the need for an exchange wire or adding a **guidewire** extension to the proximal end of the **guidewire**.

Brief Summary Text - BSTX (6):

Some over-the-wire type dilatation catheters have perfusion capabilities where one or more perfusion ports are provided proximal to the dilatation balloon in fluid communication with an **guidewire** receiving inner lumen extending to the distal end of the catheter and one or more perfusion ports are preferably provided in the catheter, distal to the balloon in fluid communication with the **guidewire** receiving inner lumen. When the balloon of a dilatation catheter with perfusion capabilities is inflated to dilate a stenosis, oxygenated blood in the artery or the aorta or both, depending upon the location of the dilatation catheter within the coronary anatomy, is forced to pass through the proximal perfusion ports, through the **guidewire** receiving inner lumen of the catheter and out the distal perfusion ports. The flow of oxygenated blood downstream from the inflated balloon minimizes ischemic conditions in tissue distal to the balloon and allows for long term dilatations, e.g. 30 minutes or even several hours or more. Commercially available perfusion type dilatation catheters include the STACK PERFUSION (TM) and the ACS RX PERFUSION (TM) dilatation catheters which are sold by ACS.

Brief Summary Text - BSTX (14):

As discussed above, the distal section of the outer tubular member is preferably formed of polymer material which allows a significant elastic expansion when inflation fluid under elevated pressure is

introduced into the lumen defined at least in part by the distal section of the outer tubular member. Beyond a particular expansion, the distal section has a very limited compliance which ensures that the catheter shaft is not over inflated. The expandable portion of the outer tubular member is formed from a heat shrinkable thermoplastic polymer material, particularly an irradiated cross-linked polymer material, which has been thermally treated to a temperature of not more than about 75.degree. C., preferably not more than about 50.degree. C., above or below the crystalline **melting point** of the polymer to provide the desired expansion. It is preferred to expand the expandable distal section at the **thermal** treatment temperature, cool and then heat shrink the expanded distal section at a temperature within about 45.degree. C. to about 80.degree. C. to a diameter much smaller than the expanded diameter. Particularly suitable polymer materials for the expandable portion of the outer tubular member are polyolefinic ionomers selected from the group consisting of sodium, lithium and zinc ionomers as described in copending application Ser. No. 07/758,630, filed Sep. 12, 1991, entitled FORMED IN PLACE BALLOON FOR VASCULAR CATHETER. The preferred polyolefinic ionomers include those sold under the trademark Surlyn.RTM. by E. I. DuPont, deNemours & Co. and particularly zinc ionomers 8020/IBE and 9020, sodium ionomers 8920 and 8940 and lithium ionomers 7930 and 7940 (DuPont product designations). Other suitable heat shrinkable polymers include ethylene vinyl acetate such as ELVAX.RTM. sold by E. I. DuPont, deNemours & Co. The expandable distal section of the outer tubular member and the inflatable member may be formed from the same tubular element, with the different portions of the tubular element being given

thermomechanical
processing to provide the desired characteristics, as will be described
subsequently. The ionomer material may be extruded at a temperature between
about 250.degree. F. to about 500.degree. F., preferably about 350.degree.
F. to about 450.degree. F.

Brief Summary Text - BSTX (16):

At least about 30% but not more than about 90%, preferably not more than
80%, of the area of the inner surface of the outer tubular member takes the
shape of and is secured to the inner tubular member. The length of the secured
section of the outer tubular member may range from about 5 mm to about 40 cm or
more, but preferably ranges from about 2 to about 35 cm. While in some of the
presently preferred embodiments of the invention only a distal portion of the
outer tubular member takes the shape of and is secured to the inner tubular
member, in some instances the outer tubular member may be secured to the
underlying inner member along its entire length. The **bond** or other connection
between the inner and outer tubular members need not be continuous along the
entire secured length, but may be intermittent along the said length, so long
as a significant portion thereof is bonded or otherwise secured to the
underlying inner tubular member to ensure that the requisite portion of the
outer tubular member takes the shape of the inner tubular member. The outer
tubular member may be secured to the inner tubular member by heat or fusion
bonding, adhesive bonding, heat shrinking the outer tube onto the inner tube or
other suitable means.

Drawing Description Text - DRTX (8):

FIG. 6 is an elevational view, partially in section, of

a dilatation
catheter embodying features of the invention which is adapted for **rapid exchange** during an intravascular procedure.

Drawing Description Text - DRTX (13):
FIG. 11 is an elevational view, partially in section, of a dilatation
catheter embodying features of the invention which is adapted to perfuse
oxygenated blood distal to the inflated **balloon of the catheter** during an
intravascular procedure.

Detailed Description Text - DETX (2):
FIGS. 1-5 schematically illustrate an over-the-wire dilatation catheter
embodying features of the invention. The catheter includes an elongated
catheter shaft 10 which has an inner tubular member 11 with a **guidewire**
receiving inner lumen 12, an outer tubular member 13 disposed about the inner
tubular member and defining therebetween annular inflation lumen 14 which
extends through the proximal portion of the catheter shaft. An adapter 15 is
secured to the proximal ends of the inner and outer tubular members 11 and 13.
An inflatable member or balloon 16 is formed as part of the outer tubular
member 13 with the distal end of the inflatable member secured to the distal
end of the inner tubular member 11. The inflatable member 16 and the distal
expandable portion 17 of the shaft 10 may be formed from the same tubing as the
proximal portion of the outer tubular member 13 as shown in FIG. 1 or they may
be made separately and secured to the distal end of the proximal portion of the
outer tubular member.

Detailed Description Text - DETX (4):
The use of the dilatation catheter shown in FIGS. 1-5

generally follows
conventional PTCA practices with over-the-wire dilatation catheters as
described in the BACKGROUND OF THE INVENTION. The proximal end of **guidewire** 21
is backloaded into the inner lumen 12 of the inner tubular member 11 of the
catheter body 10 and both the **guidewire** and the catheter are advanced together
through a guiding catheter (not shown) which has been previously disposed
within the patient's arterial system, with the distal end of the guiding
catheter seated within the ostium of the desired coronary artery and the
proximal end thereof extending out of the patient. The **guidewire** 21 is first
advanced out the distal end of the guiding catheter into the patient's coronary
artery until its distal extremity extends beyond the lesion to be dilated, and
then the dilatation catheter is advanced over the **guidewire**, which is being
held in its position, until the inflatable member 16 on the dilatation catheter
is properly disposed within the stenotic region so that the lesion can be
dilated upon the inflation thereof. After the dilatation, the inflatable
member 16 is deflated and the catheter and the **guidewire** are withdrawn from the
patient. If further treatment or diagnosis is to be conducted, the **guidewire**
21 can be replaced with an exchange wire before removing the dilatation
catheter so that the first catheter can be removed and another advanced into
the desired location over the exchange wire or an extension wire can be
attached to the proximal end of the **guidewire** in place to perform essentially
the same function. See the discussion of exchange wires and extension wires in
U.S. Pat. No. 4,827,941 (Taylor et al.) which is incorporated herein by
reference.

Detailed Description Text - DETX (5):
FIGS. 6-10 schematically illustrate another dilatation catheter embodying features of the invention which is adapted for **rapid exchange** during an angioplasty procedure. The catheter includes a catheter shaft 30 having a distal shaft section 31 and a proximal shaft section 32. The proximal section 32 has an outer plastic tubular jacket or coating 33 which fits tightly, e.g. is shrunk fit, onto a high strength tubular element 34 which may be formed of hypotubing. The distal section 31 also includes an expandable outer tubular member 35 which is disposed about the inner tubular member 36 with a very thin annular inflation lumen 37 disposed between the inner and outer tubular member when the latter is in an uninflated condition. As shown in phantom in FIGS. 6, 9 and 1 0, upon the introduction of inflation liquid under pressure into the lumen 37, the outer tubular member 35 expands along with the inflatable member or balloon 38 as shown. Upon the withdrawal of the inflation fluid, the outer tubular member 35 and the inflatable member 38 contract by elastic recoil to a much smaller outer transverse dimension, usually the same size or just slightly larger than the original uninflated dimensions.

Detailed Description Text - DETX (7):
Guidewire 41, which may be of conventional construction, extends through the inner lumen 42 of the inner tubular member 36 and out the proximal **guidewire** port 43 in the proximal end of the inner tubular member and a distal **guidewire** port 44 in the distal end of the inner tubular member. A flexible coil 45 is provided on the distal end of the **guidewire** 41.

Detailed Description Text - DETX (8):
The outer tubular member 35 is bonded to the lower

exterior portion of the
inner tubular member 36 by suitable means such as heat bonding or adhesives and
a slit is 46 is provided through the bonded walls thereof from the proximal
guidewire port 43 to a more distal location 47 to facilitate removal of the
guidewire.

Detailed Description Text - DETX (10):
The catheter construction of this embodiment with a relatively short inner
lumen 42 adapted to slidably receive the **guidewire** 41, eliminates the need for
using an exchange wire or a **guidewire** extension, as described in the Yock and
Horzewski et al. patents. A dual lumen type catheter shaft construction such
as described in Horzewski et al. may also be used in the portion of the
catheter proximal to the proximal **guidewire** port 43.

Detailed Description Text - DETX (11):
There are at least two modes of inserting the dilatation catheter of the
embodiment shown in FIGS. 6-10 into the patient's coronary anatomy. The first
method is for the most part the same as in the prior over-the-wire embodiment,
namely, the **guidewire** 41 is preloaded into the short inner lumen 42 of the
inner tubular member 36 and both are advanced through a guiding catheter (not
shown) previously disposed within the patient's arterial system with the distal
end of the guiding catheter seated within the ostium of a coronary artery as
described in the BACKGROUND OF THE INVENTION. The second mode, frequently
called the "bare wire" technique, involves first advancing a **guidewire** 41
through the guiding catheter and out the distal end thereof until it is
positioned within the patient's coronary artery across the lesion to be
dilated. The proximal end of the **guidewire** 41, which is

outside the patient,
is backloaded, i.e. inserted, through the distal **guidewire** port 44 into the
short inner lumen 42 of the inner tubular member 36 and advanced proximally
therein until it exits the proximal **guidewire** port 43. The proximal end of the
guidewire 41 is held in place while the catheter is advanced over the **guidewire**
through the patient's vascular system until the dilatation balloon 38 on the
catheter is positioned across the stenotic region so that the stenosis will be
dilated upon the inflation of the balloon. After the dilatation of the lesion,
the balloon 38 is deflated and then the catheter may be removed from the
patient's artery. If other diagnostic or therapeutic procedures are
contemplated or are possible, the catheter is slidably removed over the
guidewire 41, leaving the **guidewire** in place, so that other catheters can be
advanced over the inplace **guidewire** in a similar manner without the need for
exchange wires or **guidewire** extensions.

Detailed Description Text - DETX (15):
The dilatation catheter shown in FIGS. 11-15 may be modified by providing a
guidewire port at the proximal to the expandable distal section 57, as shown in
FIGS. 6-10. However, the **guidewire** port should be spaced sufficiently far
proximally from the portion of the bonded distal section 57 having the
perfusion ports 60 so that the **guidewire** can be pulled proximally and remain
within the inner lumen 52 while the balloon 56 is inflated during the
dilatation but not interfere with the flow of blood through the perfusion ports
60 and 63 and the inner lumen 52. Alternatively, means can be provided within
the inner lumen 52 proximal to the perfusion ports 60 to grasp the **guidewire** to

hold the **guidewire** in position while blood passes through the inner lumen 52.
After the angioplasty procedure is completed, the **guidewire** can then be
advanced distally through the inner lumen 52 and out the distal end thereof in
order to maintain access to the lesion in case further treatment or diagnosis
is necessary or desirable.

Detailed Description Text - DETX (16):
The above described catheters may be made by conventional techniques well
known to those skilled in the art such as references incorporated herein by
reference. The various components of the catheters and **guidewires** of the
invention, unless otherwise discussed, can be formed from a wide variety of
conventional materials. The catheter shaft proximal to the expandable distal
section may be made from a variety of polymeric materials including
polyethylene, polyimide, polyvinyl chloride and zinc, lithium and sodium
olefinic ionomers, such as Surlyn.RTM. sold by E. I. DuPont, deNemours & Co.
The balloon and the distal portion of the outer tubular member which forms the
inflatable unbonded portion may be made from polyethylene, polyethylene
terephthalate, olefinic ionomers and other relatively inelastic polymers and
other materials, as described in the aforementioned application Ser. No.
07/758,630.

Detailed Description Text - DETX (18):
The following example is given to further illustrate features of the
invention. An outer tubular member for a dilatation catheter was prepared
having a structure essentially as shown in FIGS. 1-3 and made of Surlyn.RTM.
(8020 grade), a zinc ionomer supplied by the E. I. DuPont, deNemours & Company.

The outer tubular member had an OD of about 0.037 inch (0.94 mm) and an ID of about 0.025 inch (0.61 mm), i.e. a wall thickness of about 0.006 inch (0.15 mm) over essentially its entire length. The outer tubular member 14 was irradiated (gamma radiation) at a level of about 45 to 55 mrads in order to cross-link essentially the entire polymeric tube. The distal portion of the polymerized tubular member which was to become the expandable distal portion was subjected to a **thermal** treatment at about 250.degree. F. for a period of about 20 seconds while applying tension in the longitudinal direction in order to develop a significant level of longitudinal orientation in the inflatable portion. After the thermally treated inflatable portion of the tubular member had cooled to room temperature, the dilatation catheter 10 was assembled. The relationship between the outer diameter of the expandable section and the fluid pressure is represented in FIG. 16 by curve A. As is evident, at pressures from up to about 8 atmospheres, the change in the outer diameter of the inflatable section is relatively small, indicating that the material has little compliance within this pressure range. At pressures from about 8 to about 12 atmospheres there is a substantial expansion in the elastic mode. At internal pressures above about 12 atmospheres the expansion of the expandable section 17 was quite small, i.e. it was relatively noncompliant, and the expansion was essentially linear with respect to the interior pressure within the inflatable section. Upon deflation, the tubular section elasticly contracts to a much smaller transverse cross section, preferably to essentially the same starting transverse dimensions.

Detailed Description Text - DETX (21):

Various modifications can be made to the present invention. For example, with the aforementioned preferred embodiment only the distal portion of the outer tubular member 14 that was to form the expandable distal section 17 was subjected to the heat treatment. If desired, the entire outer tubular member 14 can be given a **thermal** treatment to develop the characteristics of elastic expansion but the exterior of the non-inflatable portion of the outer tubular member may be provided with an inelastic jacket or coating so that only the inflatable section 16 inflates when subjected to internal pressure. Other modifications include forming the inflatable section of an outer tubular member in accordance with the invention and secure the inflatable section to a catheter shaft of different material or the same material with differing properties. The preexpansion of the expandable distal section during the **thermal** treatment before heat shrinking the expanded section also decreases the rate of increase of the expansion, but it does not substantially change the second pressure range in which the material is relatively noncompliant.

Detailed Description Text - DETX (22):

The distal sections of the outer tubular members may be formed by heat shrinking them with some means such as a mandrel between the inner and outer tubular members to form the expandable unbonded portion. A fusion **bond** between the inner and outer tubular members is preferred, particularly in those embodiments which have perfusion ports which pass through the bonded walls, because such **bonds** prevent delamination of the bonded walls. A mandrel may be inserted into the inner lumen of the inner tubular member to support the latter during the heat bonding of the outer tubular member

thereon. Alternate methods
may be employed to make the distal section. For example, the distal part of
the outer tubular member may be preformed into the desired shape and then be
adhesively bonded to the exterior of the inner tubular member.

Claims Text - CLTX (6):
4. The intraluminal catheter of claim 2 wherein the second tubular member
as a distal end, a **guidewire** port in the distal end, a **guidewire** receiving
inner lumen extending therein to the **guidewire** port in the distal end of the
second tubular member.

Claims Text - CLTX (8):
6. The intraluminal catheter of claim 4 including a **guidewire** port in the
catheter shaft which is in fluid communication with the inner lumen of the
second tubular member and which is spaced a short distance proximally from the
inflatable member and a substantial distance distally from the proximal end of
the catheter shaft.

Claims Text - CLTX (24):
18. The elongated catheter of claim 17 including a second **guidewire**
receiving port which extends through the secured sections of the outer tubular
member and the inner tubular member and which is in communication with the
first inner lumen of the inner tubular member.

Claims Text - CLTX (35):
25. The elongated catheter of claim 24 including a second **guidewire**
receiving port which extends through the secured sections of the inner tubular
member and the outer tubular member and which is in communication with the

first inner lumen of the inner tubular member.